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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/554,043

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Ivan Plavec

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EXAMINER

CLOW, LORI A

ART UNIT

PAPER NUMBER

1631

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/554,043	PLAVEC ET AL.	
	Examiner	Art Unit	
	LORI A. CLOW	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 January 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10/19/2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/28/2007; 1/28/2008</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claim Status

Claims 1-10 are currently pending an under exam herein.

Priority

Priority to US Provisional Application 60/465,152, filed 23 April 2003 is acknowledged.

Information Disclosure Statement

The Information Disclosure Statements filed 28 March 2007 and 28 January 2008 have been considered. Signed copies of PTO Forms 1449 are included with this Office Action.

Drawings

New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because Figures 3, 6, 7, 8 (a) and (b) are difficult to read either because the type is too dark or too blurry. Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

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Specification

Applicant is hereby reminded to update priority information in the first paragraph of the Specification and to update all US Patent Application numbers in the Specification with the correct status (i.e., abandoned, now Patent No. x,xxx,xxx etc...).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 recites, “exposing a set of recombinant cells to at least one factor that activates or inhibits” in the first step. In forth step of the method, the claim recites, “determining if said over or under-expresses gene in one of said pathways responds to said activators”. IT is unclear if “activators” in this context refers back to both the factor that activates and inhibits or if activators refers to just the factor that activates. Clarification is requested through clearer claim language.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-10 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 01/67103 (hereinafter "Berg et al."; PTO Form 1449 Reference).

The instant claims are drawn to determining components of a signaling pathway or alternatively to determining the presence of an interaction between a first and second pathway or ordering components of a pathway or to determining the mechanism of action of a pathway including steps of exposing a set of recombinant cells to at least one factor that activates or inhibits said signaling pathway; recording changes in cellular parameter readouts; deriving a functional profile from the changes; and clustering genes into similar pathways or determining over expressed or under-expressed genes in the pathway or epistatic relationships of the pathways.

In regard to claim 1, Berg et al. teach a method whereby components of signaling pathways (see legends of Figures 16 and 17). Berg teaches cells that are not genetically altered and cells that have been genetically altered by transfection or transduction with recombinant genes or by antisense technology (page 20). The method further comprises a step of exposing a set of recombinant cells to at least one factor that activates or inhibits the pathway (Examples 10 and 11 wherein HUVEC cells are transfected with recombinant vectors comprising members Bcl-3 and Bcl-xL that were overexpressed in the cells and are members of a signaling pathway, page 78-80). Berg et al. teach a step of recording changes in at least two different cellular parameter readouts after exposure (ICAM-1, VCAM-1 and MIG, page 80). The method comprises deriving a functional profile (a biomap-page 15-17) from the changes in parameter

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readout data (page 79, line 21 and page 80, line 22). The method further comprises clustering (see “Data Analysis section at pages 41-43 and Figures 2 and 4C).

In regard to claim 2, Berg et al. teach a method for determining the presence of an interaction between a first and a second signaling pathway comprising exposing recombinant cells to activating or inhibiting factors, recording changes in at least two cellular parameters, deriving a functional profile from the changes in parameters, and determining if one gene in a pathway responds similarly to another gene in a different pathway (Example 11, pages 79-80).

In regard to claim 3, Berg et al. teach a method of ordering the components of a signaling pathway comprising steps of exposing cells to a first inhibitor of the signaling pathway, exposing cells to a second inhibitor of the pathway, recording changes in at least two different parameters, and determining a relationship between components and inhibitors of the pathway (Examples on page 60 and page 80).

In regard to claim 4, Berg et al. disclose a method of determining the mechanism of action for a test compound on a signaling pathway comprising steps of exposing recombinant cells to a test compound, recording changes in at least two cellular parameters after the exposure, deriving a functional profile, comparing the profile with that of a control compound, and determining a comparable functional profile of the test compound (pages 64-65; Table 1.; page 67; Figures 4A-C). Berg et al. teach that the example on page 64-67 demonstrates that the biomaps (functional profiles) are useful in distinguishing the mode of action of candidate compounds, so as to know whether combinations of compounds act on the same or different pathways (page 68).

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In regard to claim 5, Berg teaches a factor that activates or inhibits a signaling pathway (page 61, lines 24-25).

In regard to claims 6-8, Berg et al. teach under-expression of a target gene as a result of exposure to an agent (Figure 2B).

In regard to claim 9, Berg et al teach at least four cell parameters (page 59, lines 17-18).

In regard to claim 10, Berg et al. teach ordering functional plots (biomaps) in graphs wherein the graphs comprise annotations (page 16). It is known in the art that annotated graphics (plots) represent two dimensional scaling plots. Berg et al. also disclose cluster plots (Figures 2 and 4).

As per the teachings above, Berg et al. anticipate each of said claims 1-10.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re*

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Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claims 1-10 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-22 of U.S. Patent No. 7,266,458. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to have analyzed said biomaps by a pattern recognition algorithm for determining the presence of a variation and effect of a genetic agent on the cellular signaling pathways.

2. Claims 1-10 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5 and 14-16 of U.S. Patent No. 6,656,695. Although the conflicting claims are not identical, they are not patentably distinct from each other because both are directed to determining the activity of a biologically active agent according to its effect on cellular signaling pathways involving contacting, recording changes, deriving a biomap dataset, and comparing limitations.

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3. Claims 1-10 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 6,763,307. Although the conflicting claims are not identical, they are not patentably distinct from each other because both are directed to determining activity of a biologically active agent (therapeutic agent) via contacting, measuring, deriving a biomap and comparing limitations. The detailed description of US 6,763,307 states test cells may include endothelial cells.

4. Claims 1-10 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 10, 13-15, 17, 19 28-29, 33-35 of copending Application No. 10/220,999. Although the conflicting claims are not identical, they are not patentably distinct from each other because both are directed to determining the activity of a biologically active agent according to its effect on cellular signaling pathways involving contacting, recording changes, deriving a biomap dataset, and comparing limitations. Application 10/220,999 states cells used in the assays may be a mixture of cell types.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

5. Claims 1-10 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 17 and 19-22 of copending Application No. 10/716,349. Although the conflicting claims are not identical, they are not patentably distinct from each other because both are directed to determining the activity of a biologically active agent involving contacting, recording changes, deriving a biomap dataset (produce a biological dataset profile), and comparing limitations. Application 10/716,349 states cells used in the assays may be a mixture of cell types and endothelial cells.

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

6. Claims 1-10 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4-8, and 13-14 of copending Application No. 10/856,564. Although the conflicting claims are not identical, they are not patentably distinct from each other because both are directed to determining the activity of a biologically active agent involving contacting, recording changes, deriving a biomap dataset, and comparing limitations.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

7. Claims 1-10 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 33-34, 38-43, 46-49 of copending Application No. 11/929,790. Although the conflicting claims are not identical, they are not patentably distinct from each other because both are directed to determining the activity of a biologically active agent involving contacting, recording changes, deriving a biomap dataset, and comparing limitations.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

8. Claims 1-10 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 17-29 of copending Application No. 11/929,841. Although the conflicting claims are not identical, they are not patentably distinct from each other because both are directed to determining the activity of a biologically active

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agent involving contacting, recording changes, deriving a biomap dataset, and comparing limitations.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

9. Claims 1-10 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-12 of copending Application No. 10/570,081. Although the conflicting claims are not identical, they are not patentably distinct from each other because both are directed to determining the activity of a biologically active agent involving contacting, recording changes, deriving a biomap dataset, and comparing limitations. The instant application describes transfection, inflammation associated pathway , and use of cancer cells.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

10. Claims 1-10 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 4-9 of copending Application No. 10/554,043. Although the conflicting claims are not identical, they are not patentably distinct from each other because both are directed to determining the activity of a biologically active agent involving contacting, recording changes, deriving a biomap dataset, and comparing limitations.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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Conclusion

No claims are allowed.

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central Fax Center Number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (571) 272-0715. The examiner can normally be reached on Monday-Friday from 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached on (571) 272-0720.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

March 3, 2010

/Lori A. Clow, Ph.D./

Primary Patent Examiner

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